



NCI-FREDERICK
Institutional Biosafety Committee

Minutes
November 17, 2009
NCI-Frederick

Introduction

The NCI-Frederick Institutional Biosafety Committee was convened at 12:05 p.m. in the Building 549 Executive Board Room with the following members in attendance:

Dr. Dan McVicar, Chair; Ms. Theresa Bell, IBC Secretary and Biosafety Officer; Dr. Serguei Kozlov; Mr. Lucien Winegar; Ms. Alberta Peugeot; Reverend David Betzner; Dr. Stephen Creekmore; Dr. Bruce Crise; Dr. Randall Morin

Members not in attendance: Mr. Scott Jendrek; Dr. Eric Freed; Dr. Michael Baseler; Dr. Stephen Hughes Dr. David Garfinkel; Dr. Melinda Hollingshead; Dr. Henry Hearn; Ms. Dianna Conrad; Ms. Kim DiGiandomenico

Others in attendance: Dr. Scott Keimig, Ms. Karen Barber, Mr. Bill Brady (VCMP); Dr. Lino Tassarollo and Erkan Kiris

Theresa Bell introduced the new IBC Administrator, Kim DiGiandomenico, to the committee. Ms. Bell also introduced Karen Barber, the occupational safety specialist who has been assisting with the IBC preliminary reviews and who will be the primary contact while Ms. Bell is on maternity leave. Dr. McVicar also informed the committee that he has met with both Ms. Bell and Ms. DiGiandomenico regarding improvements that could be made to the committee and overall IBC registration process. Key action items were identified during this meeting and status updates will be brought to the IBC as they develop.

Minutes

The August 18, 2009 and September 15, 2009 meeting minutes were approved as written. (A motion and 2nd were made. FOR: 9 AGAINST: 0 ABSTAIN: 0)

Accident Reviews

Two needlesticks occurred since the previous IBC meeting. On 11/12/09, an investigator was washing a syringe used to shear LnCap cells (human prostate cancer cells) with water. The event was reported to OHS and the investigation is still active, as it was not clear that the researcher had not been exposed, as had been indicated by the supervisor.

The second accident occurred on 11/16/09 when a laboratory technician was reusing a needle to dose animals. The needle was potentially contaminated with 2 oncogenes in a plasmid vector system; however, upon investigation, it did not appear that the oncogenes could be

mobilized. Theresa Bell will be meeting with the lab supervisor to discuss current protocols and what could be changed to avoid future needle sticks.

Review Of Protocols

New IBC Registrations

09-55 (Sandra Ruscetti) *Development of Animal Models for Xenotropic MuLV-Related Virus (XMRV)*

This investigator is conducting research with XMRV, Xenotropic Murine Leukemia Virus-related virus. XMRV has been isolated from human biological samples, and several reports associate the virus with familial and sporadic prostate cancer as well as chronic fatigue symptom. After much discussion, the committee requested for Dr. Ruscetti to address/confirm the following:

1. Update the protocol summary on the first page of the form to include the co-infection experiments;
2. Describe how lab staff will be trained regarding the safety issues of the proposed research;
3. Provide more information on the pMX backbone as well as the packaging cell lines;
4. Include in lab protocols that a containment centrifuge should be used with experiments and note that the centrifuge rotor and/or tubes should only be loaded and unloaded in a biological safety cabinet; and
5. Prior to commencing experiments, develop an XMRV post-exposure plan in the event that a lab acquired exposure results from one of the outlined procedures in the registration

Once these items are addressed, the IBC will release their approval, via the biosafety office. No further comments were made. A motion and second were made to approve the registration pending the responses to the aforementioned questions. FOR: 9 AGAINST: 0 ABSTAIN: 0

09-60 (Lino Tassarollo) *No title provided (BoNT/A research)*

The investigator plans to utilize mouse motor neurons treated with the botulinum toxin to develop a cell culture neurodegradation model system. The objectives are to identify signaling pathways that are responsive to nerve injury/toxication, to reveal proteomic/ phosphoproteomic changes after the injury/toxication, and lastly, to identify therapeutic compounds to enhance neuronal repair of injured cells. The lead reviewers were primarily concerned with the high concentration of the toxin stock that would need to be diluted to a usable working concentration. The PI and lead researcher on the project were unable to provide additional safety measures that would be taken to ensure that the chance of an exposure when aliquotting the stock into experimental volumes would be minimal. After much discussion, the committee requested the following information:

1. The investigator should contact the company who would be supplying the botulinum toxin to see if it could be pre-aliquotted to the experimental concentration prior to shipment;
2. If the stock cannot be pre-aliquotted, then the investigator must establish engineering controls to minimize the chance of exposure when making the working solutions and also determine if lower concentrations of the toxin could be used;
3. Inventory controls must be established and can be arranged through EHS;

4. Neutralization protocols must be established prior to experiments beginning;
5. Medical surveillance protocols should be in place prior to the initiation of experiments.

There was no additional comment from the committee. A motion and 2nd were made to defer the registration until the aforementioned questions were addressed. FOR: (9) AGAINST: (0) ABSTAIN: (0)

09-56 (Philipp Oberdoerffer) *A mechanistic link between DNA damage, chromatin, aging and cancer*

This is a new investigator who will use cloning techniques, in vitro cell-based assays and animal models to study the role of chromatin modifiers during DNA repair and the physiological consequences, such as global alterations in chromatin, which may promote age-related illness and cancer. Since the PI is not on campus yet, several questions have yet to be addressed, including:

1. disinfection procedures;
2. where the lentiviral work will be conducted and at what biosafety level; and
3. the potential for recombination events.

In addition, the animal protocol has now been submitted, which was not available when the registration was added to the agenda. The committee had no additional comment. A motion and 2nd were made to defer the registration until the aforementioned questions were addressed. FOR: (9) AGAINST: (0) ABSTAIN: (0)

09-58 (Stephen O'Brien) *Opportunistic collection of animal tissues for genetic, veterinary clinical pathology and histopathologic studies, and feline retrovirus discovery*

This investigator is part of the Laboratory of Genomic Diversity (LCD) and his submission to the IBC is to broadly cover all of their tissue collection activities including a wide array of potential tissue samples that may be made available to them in the future. Such research materials include, but are not limited to, dissection of kitten and cat carcasses archived from previous NIHAC ACUC protocols; receipt of wild Florida panther tissue and blood samples; receipt of discarded tissue samples from local veterinarians and spay clinics (typically reproductive organs, but occasionally entire dead cats), receipt of tissues and dead animals from zoos (excluding non-human primates), and the occasional collection of animals killed by vehicles (feral cats and other local wild animals). Further, they are in the process of developing a cat cancer project where they will be actively soliciting veterinary hospitals for the donation of excised cancerous tissue as well as the carcasses of cats who have succumbed to cancer for complete pathological work up.

The lead reviewers as well as the rest of the IBC had several concerns with the submission. Foremost, many of the technicians who are conducting necropsy are improperly trained minors (<18 yrs of age) who are part of the SIP program. They have not been made aware of the risks affiliated with the research, such as potential exposure to rabies virus from animal carcasses, especially those found on the roadside. Additionally, one of these minors recently had an exposure, was not listed on the employee roster and was not competent in the techniques in which he was performing.

Before considering the registration any further, the IBC wants the PI to address the committee at the January 2010 meeting and to address the following questions:

1. How is the rabies status of animals found along the roadside determined prior to beginning an experiment/dissection?
2. How are lab staff, in particular minors, made aware of the risks associated with the research and do the minors have parental consent?
3. How are training and proficiency, especially of minors, conducted and documented?

4. How does the PI address the hazards of other potentially infectious materials (OPIM) in samples that have been freeze-thawed or lysed, as these techniques do not destroy all OPIM that may be in samples?
5. How will safer sharps (i.e. retractable/disposable scalpels, blunt ended scissors, etc.) and proper disinfection techniques be incorporated into standard lab protocols?
6. How will specimens be safely transported among buildings and from collection sites? The current method of transport, in personal cars and improperly packaged and labeled containers, is not appropriate.

The discussion surrounding this registration also led to larger NCI-Frederick policy concerns regarding minors conducting research with OPIM in the laboratory. Since current policies do not specifically address OPIM and minors, several of the committee members felt that a policy change was necessary and should be submitted by both the IBC as well as EHS. There was a motion and 2nd to support a policy change that would prohibit minors from conducting *any* research with OPIM or blood borne pathogens. FOR: 3 AGAINST: 5 ABSTAIN: 1

Lastly, the committee discussed deferring the registration until the PI could further discuss the research in person at the January meeting. The committee had no additional comment. A motion and 2nd were made to defer registration until the PI could present the research protocol in person at the January 2010 meeting. FOR: (9) AGAINST: (0) ABSTAIN: (0)

Renewals

09-27 (06-49) and ASP 09027 - Howard Young *No title provided*

This renewal was deferred due to lack of response from the lead reviewers. A motion and 2nd were made to defer registration until more information was obtained. FOR: 9 AGAINST: 0 ABSTAIN: 0

09-54 (06-85) and ASP 09061 - Dennis Klinman *Infectious Pathogens used in the study of vaccines, adjuvants, and modulators of the innate immune system*

One of the lead reviewers recommended approval for this renewal; however the 2nd lead reviewer failed to provide feedback prior to the meeting. There was discussion that immunosuppressed and pregnant workers should be made aware of the risks affiliated with exposure to Listeria and Tularemia. A motion and 2nd were made to release IBC approval as long as the 2nd lead reviewer concurred. FOR: 9 AGAINST: 0 ABSTAIN: 0

09-59 (P160192DKB04) - Douglas Kuhns *Work with EBV*

This renewal was deferred due to lack of response from the PI regarding suggested and required revisions. A motion and 2nd were made to defer registration until the information was obtained. FOR: 9 AGAINST: 0 ABSTAIN: 0

Amendments

18 amendments were processed between the October and November meetings. The only outstanding item included:

08-75 (D. Fitzgerald) Pending comments from lead reviewer

All other amendments submitted at this time have been approved.

Outstanding Items

07-60 Vaccine Clinical Materials Program (VPP) - *potential aerosol sources document*

Mr. Bill Brady, safety officer at the VPP, informed the committee that updates to the VPP procedures were provided via sharepoint, based on the IBC recommendations from the October meeting. He wishes to demonstrate the new engineering controls to EHS as well as the IBC as soon as they are in place. If the IBC has any comments regarding the new procedures, they can post them to sharepoint and Theresa Bell will compile them, repost to sharepoint, and also provide them to Mr. Brady.

The meeting was adjourned at 2:15pm.

Theresa D. Bell, MPH, CBSP
IBC Secretary
Biological Safety Officer, EHS

Date

APPROVED:

Dan McVicar, Ph.D.
Chairman, NCI-Frederick IBC

Date

xc: Dr. Reynolds
Mr. Ramos
Dr. Arthur
Mr. Bufter